IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| IN RE: ZOSTAVAX (ZOSTER VACCINE LIVE) PRODUCTS LIABILITY LITIGATION | : | MDL NO. 2848<br><br>CIVIL ACTION NO. 18-md-2848 |
| THIS DOCUMENT RELATES TO:<br><br>JOHN MICHAEL BUSH and JOHNNY MITCHELL v. MERCK & CO., INC., et al.<br>Civil Action No. 19-1117<br><br>RICHARD DOMAN and MAUREEN M. DOMAN v. MERCK & CO., INC., et al.<br>Civil Action No. 18-20118<br><br>DAVID R. ELMEGREEN as Trustee of THE SUE A. ELMEGREEN TRUST v. MERCK & CO., INC., et al.<br>Civil Action No. 17-2044<br><br>JOHN NIEDZIALOWSKI and KATHERINE NIEDZIALOWSKI v. MERCK & CO., INC., et al.<br>Civil Action No. 19-20025<br><br>EMILY SANSONE v. MERCK & CO., INC., et al.<br>Civil Action No. 18-20114 | : | |

MEMORANDUM IN SUPPORT OF PRETRIAL ORDER NO. 402

Bartle, J. November 10, 2021

Before the court are five bellwether strict liability and negligence actions brought respectively by John Michael Bush, Richard Doman, David R. Elmegreen as Trustee of the Sue A.

Elmegreen Trust, John Niedzialowski, and Emily Sansome.[1] These actions are part of the Multidistrict Litigation involving Zostavax, a vaccine developed by defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. ("Merck") to prevent shingles, that is herpes zoster. In a word, plaintiffs assert that Zostavax, rather than preventing, caused them to contract shingles. Defendants move for summary judgment based on federal preemption of plaintiffs' state law design defect claims.[2]

Under Rule 56(a) of the Federal Rules of Civil Procedure, a party may move for summary judgment on a claim or defense or a part of a claim or defense. The court may grant partial summary judgment "if the movant shows that there is no genuine dispute of material fact and the movant is entitled to judgment as a matter of law" on a particular legal issue. A factual dispute is genuine if the evidence is such that a reasonable factfinder could return a verdict for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). A factual dispute is material if it might affect the

1. The additional plaintiffs in several of these cases are spouses who claim loss of consortium.

2. The five plaintiffs rely on the following state law: John Michael Bush on Georgia law; Richard Doman on Colorado law; Sue Elmegreen on California law; John Niedzialowski on New York law; and Emily Sansone on Florida law. Merck does not challenge that each state has a cause of action for a defective design in products sold or consumed within its borders and does not argue that the varying state laws affect its preemption analysis.

outcome of the suit under governing law. Id. at 248. The court views the facts and draws all inferences in favor of the nonmoving party. See In re Flat Glass Antitrust Litig., 385 F.3d 350, 357 (3d Cir. 2004).

Merck first submitted its Investigational New Drug Application for Zostavax to the Federal Food and Drug Administration ("FDA") on September 19, 1996. The FDA approved the vaccine on May 25, 2006. The vaccine is designed for adults 50 years and older. It is approximately 50% effective, wanes over time, and is less effective as the recipient ages. It is intended to induce an immunity response to shingles and not to cause shingles in order to effect immunity.

One of the plaintiffs' claims is that Zostavax was defectively designed because it contains a live-attenuated virus, that is, a weakened form of the wild type virus found in everyone who has had chickenpox. Plaintiffs maintain that Merck should have originally submitted a safer drug to the FDA for approval and particularly one without a live-attenuated virus such as Shingrix later developed by GlaxoSmithKline to prevent shingles. Shingrix was approved by the FDA in 2017, eleven years after the FDA approved Zostavax. Plaintiffs allege that defendants could have designed Zostavax in compliance with their duties under state law before FDA approval in 2006. Plaintiffs

do not argue liability based on the failure of Merck to have redesigned Zostavax after FDA approval.

Federal preemption on which Merck relies arises from the Supremacy Clause of the Constitution which provides that the "Constitution and the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. State law is preempted when Congress expressly provides for preemption in a particular statute. Altria Group, Inc. v. Good, 555 U.S. 70, 76 (2008). Preemption also exists where it is impossible for a party to comply with both federal and state requirements. Where federal and state law conflict, state law is a nullity. Fla. Lime & Avocado Growers v. Paul, 373 U.S. 132, 142-43 (1963). Finally, preemption comes into play where state law creates "an unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Wyeth v. Levine, 555 U.S. 555, 563-64 (2009) (internal quotation marks and citation omitted). In its analysis, the court must always be mindful of the strong presumption against preemption in the areas of traditional state regulation to protect health and safety. Altria, 555 U.S. at 77; Fellner v. Tri-Union Seafoods, L.L.C., 539 F.3d 237, 247-48 (3d Cir. 2008).

Merck relies on impossibility preemption which the Supreme Court has characterized as "a demanding defense." Wyeth, 555 U.S. at 573. Merck maintains that it was not possible for it to comply with the design requirements of both federal and state law. The issue of impossibility preemption is a matter of law to be decided by the court with no role for a jury. Merck Sharp & Dohme Corp. v. Albrecht, 193 S. Ct. 1668, 1680 (2019).

The seminal case in the area of preemption involving prescription drugs is Wyeth v. Levine, supra. There the Supreme Court held that federal preemption did not preclude an action against Wyeth under Vermont law for failure to provide an adequate warning of the risk of Wyeth's brand-name drug Phenegran used to treat nausea. Because it was injected incorrectly, plaintiff developed gangrene, and a hand and forearm had to be amputated.

The FDA had deemed the warnings sufficient when it approved the drug application and later when it approved changes in the drug labeling. Nonetheless, the Court held that Wyeth at all times "bears responsibility" for the contents of its labels. 555 U.S. at 570-71. While the FDA retains authority to reject label changes, state law was not preempted since there was not clear evidence that the FDA would have rejected a label change so as to make it impossible for Wyeth to do so. Id. at 571.

Wyeth also argued that a state law duty to provide a stronger label "would obstruct the purposes and objectives of federal drug labeling." Id. at 573. In denying preemption on this ground, the Court reviewed the 70-year history of the Food, Drug, and Cosmetics Act and noted that Congress did not enact express preemption. In the Court's view, if Congress thought state law claims "posed an obstacle to its objectives," it would have expressly preempted state law. Id. at 574. Its silence on the subject "is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." Id. at 575. Significantly, it noted that Congress enacted express preemption for medical devices in 1976 but has declined to do so for prescription drugs. Id. at 574.

Merck relies on two later Supreme Court decisions to support its preemption argument. The first is PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011). The plaintiffs sued a generic drug manufacturer under Louisiana law for personal injuries suffered from a drug designed to speed the movement of food through the digestive system. Plaintiffs claimed that defendant was liable for failure to provide adequate warnings on its generic drug. The Supreme Court held that the lawsuits failed because of impossibility preemption. The Court reviewed the statutory and regulatory scheme for generic drugs which require that generic drug manufacturers use the same warning labels and

same design for generic drugs as exist with respect to the corresponding brand-name drugs. The generic manufacturer has no other choice. Thus it cannot comply both with the federal requirement and with state law that would mandate stronger warnings. The Court distinguished Wyeth which involved a brand-name drug where the manufacturer of its own volition could comply with both state and federal law. Mensing, 564 U.S. at 624.

Merck also cites Mutual Pharmaceutical Co., Inc. v. Bartlett, 570 U.S. 472 (2013). In this action plaintiff alleged that a generic drug manufacturer was liable under New Hampshire law for her serious personal injuries resulting from a design defect of its generic nonsteroidal anti-inflammatory drug. Since the manufacturer under federal law must follow the design of the brand-name drug and could not change its design, the case evolved into a claim for failure to provide an adequate warning. Citing Mensing, the Supreme Court held that state law defective design claims turning on the adequacy of the drug warnings were preempted. It was not possible under federal law to change either the design or label of a generic drug and thus it was not possible to conform to state law.

The Court in Bartlett rejected the argument that to escape the impossibility predicament the manufacturer could stop selling the drug. As the Court stated, preemption cases

"presume that an actor seeking to satisfy both his federal-and state-law obligations" is not required to cease sales of its product altogether in order to avoid liability. 570 U.S. at 488.

Merck's reliance on Mensing and Bartlett is misplaced. First, those cases concerned generic drugs which are subject to rigid federal statutory and regulatory requirements giving the generic manufacturer no alternative but to adhere to the design and labeling of the analogous brand-name drug. Zostavax, by contrast, is a brand-name drug subject to a different and more flexible protocol. See Crockett v. Luitpold Pharm., Inc., Civ. A. No. 19-276, 2020 WL 433367, at *8 (E.D. Pa. Jan. 28, 2020); In re Tylenol (Acetaminophen) Mktg., MDL No. 2436, 2015 WL 7075949, at *21 (E.D. Pa. Nov. 13, 2015). Second, Mensing and Bartlett focused on liability for inadequate labeling or defective design at a point in time after FDA approval. Plaintiffs here pursue only pre-approval design defect claims.

Aside from Mensing and Bartlett, Merck urges the court to follow Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc., 808 F.3d 281 (6th Cir. 2015), a Sixth Circuit case directly on point, which barred a pre-approval design defect claim on the ground of impossibility preemption. There plaintiff sued defendant as a result of a stroke suffered from using its brand-name birth control patch. Her complaint included a state

law claim alleging that defendant should have submitted a safer design for the patch at the time it was first seeking FDA approval. The Court acknowledged that there was no federal law prohibiting defendant from doing so. Nonetheless, it upheld the District Court's grant of defendant's motion for summary judgment. It reasoned that it would be too attenuated to decide whether the FDA would have approved a different design. In addition, the Court rejected plaintiff's argument that defendant could avoid impossibility preemption by not selling the defective birth control patch in the first place. The Court referenced the Supreme Court's decision in Bartlett, supra, that asking the manufacturer to stop the sale of a product is not a viable argument to avoid impossibility preemption. Yates, 808 F.3d at 300.

Numerous cases outside the Sixth Circuit have disapproved of Yates insofar as it held that state law pre-FDA approval design defect claims are barred by impossibility preemption. Gaetano v. Gilead Scis., Inc., Civ. A. No. 21-1418, -- F. Supp. 3d --, 2021 WL 1153193, at *7-8 (D.N.J. Mar. 26, 2021); Crockett, 2020 WL 433367, at *8; Holley v. Gilead Scis., Inc., 379 F. Supp. 3d 809, 824-25 (N.D. Cal. 2019); Young v. Bristol-Myers Squibb Co., Civ. A. No. 16-108, 2017 WL 706320, at *7 (N.D. Miss. Feb. 22, 2017); Guidry v. Janssen Pharm., Inc., 206 F. Supp. 3d 1187, 1208-09 (S.D. La. 2016); Sullivan v.

Aventis, Inc., Civ. A. No. 14-2939, 2015 WL 4879112, at *5-6 (S.D.N.Y. Aug. 13, 2015); Trahan v. Sandoz, Inc., Civ. A. No. 13-350, 2015 WL 2365502, at *4-6 (M.D. Fla. Mar. 26, 2015); Estate of Cassel v. ALZA Corp., Civ. A. No. 12-771, 2014 WL 856023, at *5-6 (W.D. Wisc. Mar. 5, 2014).[3]

This court finds those decisions persuasive. In Holley v. Gilead Sciences, 379 F. Supp. 3d 809 (N.D. Calif. 2019), for example, the plaintiffs suffered kidney and bone damage from a brand-name drug. The court had before it a motion to dismiss based on impossibility preemption. One of plaintiffs' state law claims alleged that defendant should have asked the FDA to approve a safer alternative when it was first before the regulatory body. The Court rejected defendant's argument that the claim was preempted. It reasoned that defendant could have complied with state law by submitting an alternative design before seeking FDA approval. Since the case was in the motion-to-dismiss stage, defendant had not presented clear evidence that the FDA would not have approved the safer version.

The Holley court also rejected the Yates analysis that it was too attenuated to assume that the FDA would approve the

3. Contra e.g., Javens v. GE Healthcare, Inc., 2020 WL 2783581, at *6 (D. Del. May 29, 2020); Gustavsen v. Alcon Labs., Inc., 272 F. Supp. 3d 241, 255 (D. Mass. 2017).

safer drug since the plaintiff had alleged that the FDA had done so by the time of the Holley lawsuit. Finally, the Court found inapplicable the argument that impossibility preemption does not apply because the defendant could have stopped selling the drug. The Court explained that plaintiff was simply saying the defendant should have acted differently before it obtained FDA approval for the drug in issue.

The Supreme Court's decision in Wyeth is controlling here. While it dealt with an inadequate warning, this court sees no difference in the analysis when the claim asserted is a pre-approval design defect. Wyeth is a stark reminder that state law still plays an important role with respect to the safety of drugs. See also Albrecht, 193 S. Ct. at 1677-78. There is nothing in federal law to prohibit a drug manufacturer from originally submitting to the FDA for approval an application for a brand-name drug with a safer design required by state law. Even Yates makes this concession. 808 F.3d at 299.

Plaintiffs maintain that the safer design of Zostavax should not have included a live-attenuated virus. While Merck raises the defense that the science did not exist to do so in the timeframe before the Zostavax application was approved, there exists genuine disputes of material fact on this issue that will have to be resolved at trial.

Merck's motion for summary judgment fails for another reason. At this stage of the proceedings, it has not come forward with clear evidence that the FDA would not have approved an application for a vaccine without a live-attenuated virus. Wyeth, 555 U.S. at 571. The absence of such evidence is not surprising as the FDA later approved Shingrix. This court rejects as a matter of law any argument that the FDA would not have approved Merck's submission of an application for a drug without a live-attenuated virus. See Albrecht, 193 S. Ct. at 1680.

The stop-selling argument Merck raises and shoots down has no applicability here. As in Holley, the plaintiffs here are simply asserting that Merck should have acted differently before it sought approval to sell Zostavax, not that it should have stopped selling it.

Accordingly, the motion of Merck for summary judgment based on preemption of plaintiffs' design defect claims will be denied.